REMARKS

Status Summary

Currently, claims 1, 2, 4-6, 21-26 and 37-40 are pending. Claims 3, 7-20 and 27-36 have been previously canceled. Claims 1, 2, 4-6, 21-26 and 37-40 presently stand rejected. Upon entry of this amendment, claim 1 will be amended. Thus, upon entry of this amendment, claims 1, 2, 4-6, 21-26, and 37-40 will be pending. Reconsideration of the application and entry of the amendment is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claim 38 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,467,793 to Ender (hereinafter, "Ender"). Claims 1, 2, 4-6, 21-26, 37 and 39-40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ender in view of U.S. Patent No. 5,709,682 to Medoff (hereinafter, "Medoff"). These rejections are respectfully traversed.

Arguments Against the Rejection of Claim 38 as Being Obvious

Claim 38 recites, in part, an intrafocal plate for securing bone fractures comprising a resilient body element formed as an integral, single piece with an elongate plate element that defines a leading ending, a trailing end, an intermediate location between the leading and trailing ends, an overhanging heel toward the trailing end, and a bottom surface with the resilient body element extending from the bottom surface of the intermediate location of the elongate plate element and in a lengthwise direction

relative to the elongate plate element beyond the terminal end of the elongate plate element.

It is asserted in the Office Action that Figure 1 of Ender shows an intrafocal plate with an elongate plate **5** and a resilient body element **4** extending downwardly from a bottom surface of the elongate plate element and from an intermediate location of the elongate plate such that an overhanging heel of the elongate plate as labeled as **17** in Figure 7 is located between the resilient body **4** and a trailing end of elongate plate. It is acknowledged in the Office Action that Ender fails to teach that the resilient body element is formed as an integral, single piece with the elongate plate element. It is asserted, however, in the Office Action that it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the intrafocal plate taught in Ender with resilient body element and the elongate plate element as an integral, single piece.

Applicant respectfully disagrees. First, Ender does not disclose, teach, or suggest an intrafocal plate. The Patent Office is respectfully reminded that an intrafocal device, by definition, is one that enters the broken bone at the fracture location. Represented in Figure 1 of Ender is an *intramedullary* device. The intramedullary device of Ender differs from the intrafocal plate recited in claim 38 of the present application in that the intramedullary device, as depicted in Figure 1 of Ender, is inserted into the bone longitudinally opposite from where the fracture is located. This very significant difference in structure and function would be well known to one skilled in the art such as an orthopaedic surgeon.

Further, it is well settle that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (See MPEP §2143.01 citing In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).) Similarly, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. (See MPEP §2143.01 citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).) In the present Office Action, the modifications suggested therein making the insert member and the nails disclosed in Ender an integral, single piece would change the principle of operation of the intramedullary device disclosed in Ender and render it unsatisfactory for its intended purpose.

Ender states that there are specific problems with using bone nails as intramedullary devices such as the unintended and undesirable enlarging of the impact hole in which the bone nails are inserted through health bone and the undesirable consequences of the nails being driven too far into the impact hole. For example, regarding the effects of creating the impact hole and driving of driving nails into the impact hole, Ender states that:

> As a rule, the impact hole is made such that the bone is first punctured and subsequently the small hole thus formed is widened by means of a three- or four-edged reamer, enlarged by means of a chisel or by means of a drill. In all these cases, parts of the bone can be split off thus enlarging the impact hole in an undesired manner. But also when forcibly driving the nails, a cortical wedge can be split off the proximal cortex by the tangential shearing stress, which results to an undesired enlargement of the impact hole, noting that the edge of the impact hole can also collapse at the forward side. Both cases result in the nails

> protruding in an uncontrolled manner and, if the fracture extends into the bone, a torsional fracture of the thigh might be produced by the surgeon.

(See, Ender at col. 1, line 63 - col. 2, line 9.)

For example, regarding a further effect of driving of driving nails into the impact hole, Ender states that:

> It can also occur that the bone nails are driven too far into the impact hole, so that the coupling member no longer contacts the outer surface of the bone or that the coupling member contacting the outer surface of the bone becomes shifted in direction to the interior of the bone because part of the edge of the hole has been broken away.

(See, Ender at col. 2, lines 10-16.)

Ender provides a litany of disastrous effects caused by allowing the bone nails to be driven too far into the impact hole, including reduction in the required tension stress of the nails, hindrance of proper placement of the nails, perforation of the condyle of the bone, penetration of the socket of the hip joint, and complications relate to the removal of such nails. (See, Ender at col. 2, lines 17-36.)

The Summary of the Invention of Ender discloses that it is the object of the invention to avoid these drawbacks by providing an intramedullary device that "essentially consists" of an insert member for inserting into an impact hole and separate bone nails for later insertion into a guiding channel of the insert member after the insert member is affixed in the impact hole. (See, Ender at col. 2, lines 40-49.) In describing the essential need and importance of having an insert member that is separate and distinct from the bone nail, the Summary of the Invention in Ender further states that:

> This insert member, which is inserted into the impact hole and is fixed therein by the fixing means, prevents the impact hole from becoming spalled when driving in the nails and thus from becoming enlarged in a disadvantageous manner and the size of the openings through which the bone nails are driven into the medullary canal is rather defined by the cross section of the guiding channel. Furthermore, by using such an insert member, the nails can be driven into the bone to such a depth that their distal end is accommodated by the insert member and thus, does not protrude, so that any irritation of the muscles and sinews is prevented and additionally, entering of the nail ends, provided with the coupling member, into the medullary canal is avoided. The forces exerted by the coupling members of the nails subjected to tension stress are rather supported by the insert member and transmitted by this insert member on the bone in an equal manner over the whole circumference of the impact hole so that even with older humans having porous bones any danger of a break down of the bone at the area of the impact hole is avoided. Finally, the nails are, on forcibly driving the nails, guided at the driving-in position by the guiding channel of the insert member, so that also when driving-in the nails there exists no danger of injuring the bone by subjecting the proximal cortex to tangential shearing stress. In view of the distal ends, provided with the coupling members and the nails being arranged within the insert member and thus being easily accessible, the nails can easily be removed from the medullary canal when using an instrument according to the invention.
>
> (See, Ender at col. 2, lines 40-49.)

Thus, Ender discloses an insert member **5** that is a separate modular component from the resilient bone nails **4** consisting of elastic material and being bent at proximal end portions that are insertable into a medullary canal **3** of a bone **1**. The insert member **5** has a guide channel **6** which is arrange such that the nails **4**, when forcibly introduced, run into the medullary canal **3** in the desired manner. The insert member **5** is provided with a flange **7** contacting the outer surface of the bone **1** to prevent the insert member **5** from entering the medullary canal for too great a distance, to prevent the impact hole from becoming spalled and enlarged by the driving in of the nails **4**, and to distribute forces exerted by the coupling members of the nails **4** subjected to tension

stress equally over the circumference of the impact hole. In order to accomplish these intended purposes, the principles of operation of the intramedullary device require that the insert member **5** is a specifically separate component from the resilient bone nails **4** to allow the insert member **5** to be inserted into and positioned around and within the impact hole before the bone nails **4** are to be inserted.

Applicant respectfully submits that the combining of the insert member and the nails of Ender into an integral, single piece would render the device of Ender unsatisfactory for its intended purposes of protecting the bone being repaired with the insert member as described above. In re Gordon is instructive because, as in the instant case, it also involved a rejection based upon a modification that would have otherwise rendered the prior art inoperable for its intended purpose. In In re Gordon, the claimed device was a blood filter assembly for use during surgery and medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation was assisted by gravity. On appeal, the Board of Patent Appeals and Interferences concluded that the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The Federal Circuit reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped

at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged. (See In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).)

Similar to the proposed modification to the filter in In re Gordon, the proposed modification to the intramedullary device disclosed in Ender would render that device unsatisfactory for its intended purpose. In particular, to modify the intramedullary device disclosed in Ender having a separate insert member and separate nails so that the device is an integral, single piece would render the intramedullary device disclosed in Ender unsatisfactory for its intended purposes. For example, the modifications would render the intramedullary device disclosed in Ender unsatisfactory for the purpose of preventing the impact hole from becoming spalled and enlarged by the driving of the nails into the bone and the purpose of distributing forces exerted by the coupling members of the nails subjected to tension stress equally over the circumference of the impact hole in the same manner as a separate and independent insert member.

Further, a clear principle of operation of the intramedullary device disclosed in Ender is to insert the insert member first into the impact hole before inserting the separate nails into the insert member to protect the bone as described above. To modify the intramedullary device disclosed in Ender having a separate insert member and separate nails so that the device is an integral, single piece would eliminate the ability of inserting the insert member into the impact hole before inserting the coupling member of the bone nails into the impact hole to protect the bone around the impact hole and prospectively prevent damage caused by over-insertion by providing a stationary strong backstop for the nails as the nail is driven into the bone as called for in

Ender. The proposed modification of Ender would thus also change the principles of operation of the intramedullary device being modified.

Therefore, for at least the reasons given above, the teachings of the Ender are not sufficient to render independent claim 38 or the claims that depend therefrom, *prima facie* obvious.

Arguments Against the Rejection of Claims 1, 5, 39 and 40 and the Claims that Depend Therefrom as Being Obvious

Independent claims 1 and 5 and claims 39 and 40 are rejected as being rendered obvious by Ender in view of Medoff. Claims 1 and 5 recite that a longitudinally extending intrafocal resilient body element is integral to a surface of a plate element adjacent to but spaced apart from a trailing end of the surface of the plate element. Therefore, as with claim 38, the resilient body element is formed as an integral, single piece with the plate element. Claims 39 and 40 depend from claim 38 and thus also include the feature of the resilient body element being formed as an integral, single piece with the elongate plate element.

As stated above, to modify the intramedullary device disclosed in Ender having a separate insert member and separate nails so that the device is an integral, single piece would render the intramedullary device disclosed in Ender unsatisfactory for its intended purposes of preventing the impact hole from becoming spalled and enlarged by the driving in of the nails and of distributing forces exerted by the coupling members of the nails subjected to tension stress equally over the circumference of the impact hole. Further, to modify the intramedullary device disclosed in Ender having a separate insert

member and separate nails so that the device is an integral, single piece would eliminate the ability of inserting the insert member into the impact hole before inserting the coupling member of the bone nails into the impact hole to protect the bone around the impact hole as called for in Ender. The proposed modification of Ender would thus change the principles of operation of the intramedullary device being modified. Medoff fails to overcome these significant shortcomings of the suggested modification of Ender as outlined above. Therefore, the teachings of the references are not sufficient to render independent claims 1 and 5, claims 2 and 4 that depend from claim 1, or claims 39 and 40, *prima facie* obvious.

Arguments Against the Rejection of Claims 6 and 21 and the Claims that Depend Therefrom as Being Obvious

Independent claims 6 and 21 are also rejected as being obvious over Ender in view of Medoff. Independent claims 6 and 21 recite that the body element has a sinuous shape and the body element has a first portion, a second portion and a third portion, wherein the first portion curves away from the plate element, the second portion curves toward the plate element and the third portion curves away from the plate element.

Applicant respectfully submits that Medoff discloses an implantable clamp for fixation of one or more bone fragments to a stable bone. The clamp has two basic functions, namely a buttress function and a clamp function. Either function may be employed depending on the fracture. The clamp as shown in Figures 2-4 of Medoff has a first part, or buttress pin, **41** having a front part bent into a buttress **49**. The first part

41 is U-shaped as viewed from the top, and is furnished with pointed projections **45** for engagement with bone cortex. The buttress pin **41** is secured to the stable bone with a bone screw **44** cooperating with a washer **46**.

Figure 5 in Medoff shows application of the buttress pin **41** of Figures 2 to 4 on a fracture. The buttress pin **41** is driven up behind the fragment **85** to push it against the adjacent cortex. In this position, the device is secured to the stable bone **81** with the bone screw **44** cooperating with the washer **46**. The pointed projections **45** help to give a stable fixation. The buttress pin **41** is stiff enough to allow the fragment **85** to be maintained in position against the opposite side of the joint. On the other hand, the buttress pin **41** is flexible enough to allow it to be removed after fracture healing without significant disruption of bone. Thus, this buttress pin **41** provides an intraosseous buttress to the cortical fragment **82** as shown in Figure 5 in Medoff. This provides a stable floor against which this cortical fragment may abut, providing additional stability to this fragment. The buttress pin **41** is capable of being used as an intraosseous buttress for an intra-articular fragment, an unstable cortical fragment, or a combination of the two.

As acceded in the Office Action, Ender fails to teach the recited features of claims 6 and 21 provided above. (See, Office Action at pages 5 and 6.) Instead, the Office Action indicates that Medoff "teaches a body element (Fig. 3) has a sinuous shape in a first plane according to a side elevation view (Fig. 3) of the body element." Using the modified Figure 5 provided below, the Office Action describes a device in Medoff with a plate element and a body element that has a first portion, a second portion, and a third portion for fixation of one or more bone fragments, wherein the first

portion curves away from the first part (see modified Fig. 5 below), the second portion curves toward the plate element (see modified Fig. 5 below), and the third portion curves away from the plate element (see modified Fig. 5 below). (See, Office Action at page 6.)

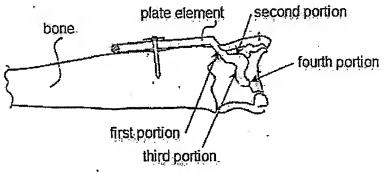

Fig. 5

(See, Office Action at page 7.)

Applicant respectfully submits that neither Ender nor Medoff discloses a plate element and a body element that has a sinuous shape such that the body element has a first portion, a second portion and a third portion, wherein the first portion curves away from the plate element, the second portion curves toward the plate element and the third portion curves away from the plate element.

The "body element" in Medoff does not have such a sinusoidal shape for the identified portions in the modified Figure 5 above provided by the United States Patent and Trademark Office. Only the buttress **49** in the device in Medoff has a shape that is close enough to possibly be considered sinuous. As can be seen in the modified Figure 5 above, the first portion in the modified Figure 5 is not curved at all. The first portion as

recited in claims 6 and 21 curves away from the plate element. The first portion in the modified Figure 5 is linear, not curved.

Additionally, the second portion in the modified Figure 5 does not curve toward the plate element as recited in claims 6 and 21. This identified second portion appears to curve further away from the plate element. Further, this identified second portion does not even reach a point where the "body element" in Medoff reaches a position that is parallel with a plane in which the plate element resides, especially when measured from the curved bottom section of this identified portion. Thus, since the bends in the part **41** and the curvature of buttress **49** of the device in Medoff are so different than the first, second, and third portions of the body element recited in claims 6 and 21, the combination of the device in Medoff with the intramedullary device in Ender does not disclose, teach, or suggest all the features recited in claims 6 and 21.

For at least these reasons, Ender and Medoff, alone or in combination, do not render obvious claims 6 and 21. Since claims 22-26 and 37 depend from claim 21, these claims are also not rendered obvious by Ender and Medoff, alone or in combination.

Summary of Arguments Against Obviousness of the Pending Claims

For the reasons set forth above, claim 38 is not rendered obvious by Ender. Further, claims 1, 2, 4-6, 21-26, 37 and 39-40 are not rendered obvious by Ender and Medoff, either alone or in combination. Accordingly, Applicant respectfully submits that the rejections of claims 1, 2, 4-6, 21-26, and 37-40 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the claims of the present application are now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. **50-0426**.

Respectfully submitted,
JENKINS, WILSON, TAYLOR, & HUNT, P.A.

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